Subject: FW: Junior Pilot Studies

Date: Friday, December 17, 2021 at 3:15:43 PM Central Standard Time

From: Snowden, Jessica

To: Brenda Salley, Ann Davis

Attachments: image001.png, Salley BUDGET TWMB ISPCTN 2021-11-30.xlsx, Salley study milestones draft

2021-11-30.docx

Brenda,

These questions & answers might be helpful for the other investigators. Would you might if I put this exchange in the shared folder?

Best,

Jessica

Jessica Snowden MD, MS, MHPTT

jsnowden@uams.edu OFFICE: 501-364-1416 CELL: 501-251-7475

Division Chief, Pediatric Infectious Disease Vice Chair for Research

Horace C. Cabe Endowed Chair in Pediatric Infectious Disease

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Associate Director for Clinical & Translational Research Arkansas Children's Research Institute

She/her/hers

Please note: I frequently send emails after hours and on the weekend. However, I do not expect email responses outside of working hours.

From: Blaisdell, Carol (NIH/OD) [E] <carol.blaisdell@nih.gov>

Sent: Friday, December 3, 2021 2:59 PM

To: McNutt, Carolyn <CMcnutt@uams.edu>; Raju, Tonse (NIH/OD) [E] <tonse.raju@nih.gov>

Cc: Fu, Linda (NIH/OD) [E] linda.fu@nih.gov>; Snowden, Jessica <JSnowden@uams.edu>; Edward Ellerbeck <EELLERBE@kumc.edu>; Ying, Jun <JYing@uams.edu>; Kristina Foster <kfoster6@kumc.edu>; Ann Davis

<adavis6@kumc.edu>; bsalley@kumc.edu

Subject: FW: Junior Pilot Studies

Dear Carolyn,

Linda forwarded me your email to Tonse, who you see if out of office. I hope I can help.

This budget making is a great example of capacity building for the network, and the questions you and Drs. Salley and Davis have asked are great ones.

Within the limits of the \$300,000 total cost budget for junior pilot proposals, the scientific proposal scope of work should fit and be justified.

RE: Site PI time—I agree with Jessica that this can be budgeted as a small amount (1% FTE or start up of ~\$3000) for the purposes of overseeing and being responsible for study start up and performance. Dr. Salley need not add such costs to her own effort required by her overall protocol leadership role. I thought one purpose of the 1% FTE some institutions have requested is for contract purposes. So with her 15% FTE that might be sufficient. If partner institutions for the subcontracts don't specify a minimum FTE, the salary support of site investigator could be built into the capitation, which is a model Industry uses.

RE: start-up costs for clinics—that can be a budgeted expense, as long as justified. Again, depends on the purpose and need.

Let me know if you have questions while Tonse is out through Dec 17.

Carol

Carol J. Blaisdell MD MEd Senior Program Officer Environmental Influences on Child Health Outcomes (ECHO) Office of the Director, National Institutes of Health Cell 240-551-9069

From: McNutt, Carolyn < CMcnutt@uams.edu > Sent: Thursday, December 2, 2021 5:22 PM

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To: Raju, Tonse (NIH/OD) [E] < tonse.raju@nih.gov>

Cc: Fu, Linda (NIH/OD) [E] <! Snowden, Jessica <! Edward Ellerbeck <! Edward Ellerbeck <! Snowden@uams.edu ; Edward Ellerbeck <! Edward Ellerbeck <! Snowden@uams.edu ; Kristina Foster <! Ann Davis <| Ann Davis <| Ann Davis | Ann Davis</a

Subject: FW: Junior Pilot Studies

Good Afternoon Tonse,

On Tuesday I had a meeting with Dr. Salley from Kansas regarding her Pilot Study Budget and a couple of questions came up that we wanted to get your feed back on. I first sent the questions to Dr. Snowden and her answer is below and included in the email.

- 1. Site PI time. Somewhere there has been two things communicated, PI effort at 1% or 3k. Linda brought up the issue of capitation and whether or not the PI time should be part of the capitation budget and she wanted us to follow up with you for the NIH position on that. Also Brenda was unsure if she could be the PI from Kansas? Just want to make sure I told her correctly that she could be. She had two site PI's listed and herself. It's entirely possible that either scenario is appropriate, just wanted some clarification.
- 2. Start- up costs for clinics, can those be budgeted? Dr. Davis thought IAMHEALTHY provided start -up costs for clinics on a fee basis again I think the number was 3K?

Thank you so much for your input.

Sincerely;

Carolyn McNutt, BBA

Associate Director of Finance Data Coordinating and Operations Center IDeA States Pediatric Network ACHRI-Slot #512-35 13 Children's Way Little Rock, Arkansas 72202



IDeA States Pediatric Network

From: Snowden, Jessica

Sent: Wednesday, December 1, 2021 2:33 PM **To:** McNutt, Carolyn < <u>CMcnutt@uams.edu</u>> **Cc:** Doville, Amy < <u>ADoville@uams.edu</u>>

Subject: RE: Junior Pilot Studies

Good questions -

It is up to them to propose what they want the site PI FTE to be. We didn't provide any specific boundaries on that. Typically, sites have asked us for at least 1% FTE even if there is a capitated piece as well. Yes, Brenda can be both (although it can be challenging to separate the roles, so we'd want to talk about how to manage that).

Yes, they can include clinic incentives if they want to.

Best,

Jessica

Jessica Snowden MD, MS, MHPTT

jsnowden@uams.edu OFFICE: 501-364-1416 CELL: 501-251-7475

Division Chief, Pediatric Infectious Disease Vice Chair for Research Horace C. Cabe Endowed Chair in Pediatric Infectious Disease University of Arkansas for Medical Sciences Principal Investigator
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She/her/hers

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From: McNutt, Carolyn < CMcnutt@uams.edu > Sent: Tuesday, November 30, 2021 3:58 PM
To: Snowden, Jessica < JSnowden@uams.edu > Cc: Doville, Amy < ADoville@uams.edu >

Subject: Junior Pilot Studies

Dear Dr. Snowden;

I met with Brenda Salley today to go over her pilot study. Linda Fu was on the call as well as Ann Davis and a few other people. A couple of questions arose and I said that I would follow up with Tonse but wanted to check with you first.

- 1. Site PI time. Somewhere there has been two things communicated, PI effort at 1% or 3k. Linda brought up the issue of capitation and whether or not the PI time should be part of the capitation budget and she wanted us to follow up with Tonse. Also Brenda was unsure if she could be the PI from Kansas? Just want to make sure I told her correctly that she could be. She had two site PI's listed and herself. It's entirely possible that either scenario is appropriate, just wanted some clarification.
- 2. Start up costs for clinics, can those be budgeted? Dr. Davis thought IAMHEALTHY provided start up costs for clinics on a fee basis again I think the number was 3K?

Thank you for your help.

Carolyn McNutt, BBA

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